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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,287	01/11/2001	Raul G. Barletta	801204-0011	9782
27910 7590 06/27/2007 STINSON MORRISON HECKER LLP ATTN: PATENT GROUP 1201 WALNUT STREET, SUITE 2800 KANSAS CITY, MO 64106-2150				
			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 06/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Office Action Summary</p>	Application No. 09/759,287	Applicant(s) BARLETTA ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6February2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-42 and 54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-42 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Pursuant to the Notice of Pre-Brief Appeal Conference Decision, the finality of the last Office Action is hereby vacated.
2. Applicants' Response to Office Action, received 7 November 2006, is acknowledged.
3. Claims 15-42 and 54 are pending and under consideration.

Rejections Maintained

4. The rejection of claims 15-42, and now newly added claim 54, under 35 U.S.C. 112, second paragraph, indefiniteness for differentiation of "growing" and "nongrowing", is withdrawn.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 15-17, 19, 20-27, 29-31, 33-41, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs et al (U.S. Pat. No. 5,773,267).

The claims are drawn to a mutant mycobacterium. The recitation of the procedures for producing the mutant mycobacterium do not impart any patentability on the composition. Therefore, any composition which fulfills the structural characteristics of the mutant mycobacterium reads on the claims. The claims are also drawn to compositions comprising at least one mycobacterium virulence determinant. Because of the open language of the claims, i.e., "comprising", the claims read on whole bacteria.

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Jacobs et al teach a mutant mycobacterium, BCG, a slow grower, nonvirulent, which has at least one mutation, ie., introduction of extraneous genetic material (Abstract; col. 6, line 23 to col. 8, line 9; claims 12-15).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 18, 28, 32, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al (U.S. Pat. No. 5,773,267).

The claims are drawn to a mutant *Mycobacterium paratuberculosis*. The recitation of the procedures for producing the mutant mycobacterium do not impart any patentably on the composition. Therefore, any composition which fulfills the structural characteristics of the mutant mycobacterium reads on the claims. The claims are also drawn to compositions comprising at least one *Mycobacterium paratuberculosis* virulence determinant. Because of the open language of the claims, i.e., "comprising", the claims read on whole bacteria.

Jacobs et al teach a mutant mycobacterium, BCG, a slow grower, nonvirulent, which has at least one mutation, ie., introduction of extraneous genetic material (Abstract; col. 6, line 23 to col. 8, line 9; claims 12-15). While Jacobs et al do not specifically teach mutant *Mycobacterium paratuberculosis*, they do teach that the methods for producing the mutant mycobacterium extend to other mycobacteria. Thus, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to make mutant *Mycobacterium paratuberculosis* for use a vaccine compositions.

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Conclusion

9. No claims are allowed.
10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

June 20, 2007